REMARKS

With entry of the present amendment, claims 11 -16, 20-29, 33, 35-37, and 40-42 are pending. Claims 10, 17-19, 30-32, and 38-39 are cancelled as directed to non-elected inventions to be pursued in separate divisional or continuation applications. Claims 2, 13-16, 22, 25, 27-29, 35 have been amended to more clearly state the invention as claimed. Claims 40-42 have been added. Support for the new claims and the amendments can be found in the specification, claims and figures as filed. Support for the amendment to the specification and claims specifying that the substitutions are numbered from the first amino acid after the signal and pro sequence of SEQ ID NO:1 is presented in the discussion of the rejection under 35 U.S.C. §112, second paragraph. Support for new claims 40-42 can be found in claims 11-13 and in the Figure 18. Support for the amendment specifying that the sequence identity is "in conserved regions common to at least 75% of family 11 xylanases " can be found in the specification as filed at least at Page 6, line 9-10. Applicants assert no new matter has been introduced by the new claims. No amendment should be construed as an acquiescence in any ground of rejection.

Traverse of the Restriction mailed 10/16/2006

In the restriction mailed 10/16/2006, the Examiner required restriction to one of inventions (A)-(AU). Applicants mistakenly assumed this was an election of species and responded accordingly. However, it is clear from the present office action mailed from the PTO on January 30, 2007 that the Examiner meant this as a restriction, not as an election of species. Thus, Applicants would like to respectfully traverse this restriction and believe it should be an election of species.

The restrictions requirement is in error because it requires division of a generic claim contrary to controlling law. The statute authorizing restriction practice, i.e., 35 U.S.C. § 121, provides no legal authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions.

The discretionary power to limit one application to one invention is no excuse at all for refusing to examine a broad generic claim—no matter how broad, which means no matter how

many independently patentable inventions may fall within it. *In re Weber* et al. 198 USPQ 328, 331 (C.C.P.A. 1978) at 334.

Instead of imposing a restriction requirement on a single claim, the Patent Office may limit initial examination to a reasonable number of species encompassed by the claim. See 37 C.F.R. §1.146. This practice strikes an appropriate balance between the concerns of the patent office regarding administrative concerns and unduly burdensome examination, and the clear constitutional and statutory rights of an inventor to claim an invention as it is contemplated. *See* MPEP (Eighth Edition August 2001, Revision 1, February 2003) at § 803.02; see also *In re Wolfrum*, 179 USPQ 620 (CCPA 1973); and, *In re Kuehl*, 177 USPQ 250 (CCPA 1973). The MPEP states that an unduly extensive and burdensome search of a generic claim justifies an election of species requirement, but says nothing about a restriction requirement of a generic claim (MPEP 808.01(a)). It is acknowledged that this section of the MPEP is headed "Restriction—Markush Claims." Nevertheless, the text is explicit that an election of species is intended.

> A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one f the members would not render the claim obvious under 35 U.S.C. 102 with respect to the other members. In applications containing claims of that nature, the examiner may require a provisional election of a single species prior to examination on the merits.
> MPEP §803.02 (emphasis supplied).

Also, the MPEP should be construed as being consistent with the case law of in re Weber and In re Haas, as reaffirmed by In re Harnisch, that 35 U.S.C.121 cannot be used to reject a single claim.

With respect to the sequence requirement (MPEP §803.04), applicants submit that it is not applicable to the present invention because the sequences in the markush group as presently claimed encode the same protein with minor variations. Thus, as claimed, the present invention is more akin to claims such as those having language comparable to: "a SEQ ID NO:X and variants thereof that have (for example) 97% sequence identity to SEQ ID NO:X." The difference in the present claim is that the specific variations are set out. As stated In the

MPEP §803.04, "...nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together."

Here, the restriction of each group into groups separated by the specific position within SEQ ID NO:1 for the substitution is inappropriate and contrary to the controlling case law of In re Weber as subsequently re-affirmed by In re Harnisch. Even if the Applicant was to pursue 47 of divisional applications, the aggregate scope of the resulting claims would not be the same as that of present claim 1. the examiner's rationale that individual claims contain many patentably distinct inventions is "no excuse at all" for purporting to restrict individual claims. In re Weber at 334. Applicants submit that the appropriate remedy for an unduly extensive and burdensome search is an election of species requirement. MPEP §808.01.

Claim Objections

The Examiner has objected to claims 11-16, 20-21, 23-24, 26-27, 29, 33 and 36 as encompassing non-elected subject matter.

Claims 11-13, 21, 23-24, 26-27, and 29 are objected to for the recitation "selected from the group .....+191" as applicants have elected a single position 144 equivalent to SEQ ID NO:1. While independent claim 27 has been amended to reflect this election, Applicants will await the Examiner's decision regarding traverse to respond to this rejection.

Rejection under 35 USC §112, second paragraph

Claims 13-16 and 20 were rejected as indefinite because they recite the mutational modification "H144C" which is confusing because the original position 144 of SEQ ID NO:1 is Aspartic acid (D) and not Histidine (H) as written. Applicants have amended the claims to recite that the " position of the substituted amino acid is numbered from the amino acid after the signal and pro sequence." This is supported by the specification and claims as filed, including the following: Figure 18 shows the Trichoderma reesei Xyl II protein SEQ ID NO:1 "including the signal and pro sequence." (see the language above SEQ ID NO:1). When the signal and pro sequence are removed (the first 33 amino acids), the numbering for the modifications starts from the next amino acid (the Gln – Q – at position 34). For example all of the mutations as designated in Claims 12-20 line up with the correct amino acid number. For example amino acid 144 is at position 144 when counting from the amino acid after the signal and pro

sequences – a histidine. Figure 2 shows the Trichoderma Xyl II protein sequence without the signal and pro sequences as "1ENX."

For further support, a reference to the oligonucleotide sequences shown in figure 3 which were used to mutagenize the xylanase at each position shows that the position of the mutation (the underlined codon) corresponds to the amino acid as numbered from after the signal and pro sequence.

Thus, with the clarifying amendment, Applicants respectfully submit that the claims and the numbering of the mutations/substitutions is definite.

Rejection under 35 USC §112, first paragraph

Claims 22-23, 24-26, 28-29, and 35-36 were rejected as not enabled for "any modified xylanase or a glycosyl hydrolase of clan C or family 11 xylanase or any polypeptide having 20 or 90% sequence identity to SEQ ID NO:1. The claims have been amended to read "having 90% (and 97%) sequence identity to SEQ ID NO:1 in conserved regions common to at least 75% of family 11 xylanases ".

The test for enablement involves identifying whether the experimentation needed to practice the invention is undue or unreasonable (*In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). There are many factors to be considered when determining whether any experimentation needed is "undue." These include the breadth of the claims, the state of the prior art, the level of predictability in the art, the amount of direction provided, and the existence of working examples.

The claims have been amended to recite the modified enzyme having at least one of the substitutions set out (2, 5, 7, 10 , 11, 16, 19, 22, 26, 28, 29, 30, 34, 36, 38 , 57, 58, 61, 63, 65, 67, 92, 93, 97, 105, 108, 110, 111, 113, 132, 143, 144, 147, 149, 151, 153, 157, 160, 162, 165, 169, 180, 184, 186, 188, 190 and +191) **and** at least 90% sequence identity with SEQ ID NO: 1 in conserved regions common to at least 75% of family 11 xylanases."

Thus, the test for enablement would involve the analysis of whether it would require undue experimentation for the skilled artisan to identify and/or produce enzymes having at least one of the substitutions to SEQ ID NO:1 set out and 90% sequence identity to SEQ ID NO:1 as claimed.

Applicants submit that an enzyme having at least one of the substitutions set out (2, 5, 7, 10 , 11, 16, 19, 22, 26, 28, 29, 30, 34, 36, 38 , 57, 58, 61, 63, 65, 67, 92, 93, 97, 105, 108, 110, 111, 113, 132, 143, 144, 147, 149, 151, 153, 157, 160, 162, 165, 169, 180, 184, 186, 188, 190 and +191) **and** at least 90% sequence identity to the enzyme of SEQ ID NO:1 in conserved regions common to at least 75% of family 11 xylanases is well within the ability of the skilled artisan to make and/or use. Such an enzyme would include any natural variants as well as conserved amino acid changes. Thus, the breadth of the claim is not undue and includes a very specific range of variants that are clearly set out and reasonably identifiable with a minimum of experimentation. Within the claims themselves, the amount of direction as to how to identify or make an enzyme for use in the method is also clearly set out in the specification. Any direction that is not provided by the teaching in the specification and claims would be supplemented by the knowledge of the skilled artisan, including methods of identifying and making variants that include natural variants and conserved amino acid changes. The identification and production of variants having 97-99% sequence identity is a process that has achieved a high level of sophistication in the field of molecular biology. Thus, it would require a very low level of experimentation to identify and/or produce such variants. Because of the sophistication, the predictability in these methods is also very high.

Thus, applicants submit that it would not require undue amount of experimentation for the skilled artisan to make and/or identify enzymes having at least one of the substitutions set out (2, 5, 7, 10 , 11, 16, 19, 22, 26, 28, 29, 30, 34, 36, 38 , 57, 58, 61, 63, 65, 67, 92, 93, 97, 105, 108, 110, 111, 113, 132, 143, 144, 147, 149, 151, 153, 157, 160, 162, 165, 169, 180, 184, 186, 188, 190 and +191) **and** at least 90% sequence identity to the enzyme of SEQ ID NO:1 in conserved regions common to at least 75% of family 11 xylanases and applicants respectfully request withdrawal of the rejection.

Applicants believe the pending claims are in condition for allowance and issuance of a formal Notice of Allowance at an early date is respectfully requested. If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (650) 846-7620.

Respectfully submitted,

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